

Dear John

Thank you for your enquiry of the 12 December 2012, to the Therapeutic Goods Administration (TGA) regarding Fluoride in drinking water.

We appreciate that you are concerned about the impact that fluoride in water may have had on your health. The most appropriate government agency to respond to your queries is the NSW Health Department. Their contact details are as follows:

New South Wales Ministry of Health
Phone: 02 9391 9000

Role of the TGA

The TGA's primary consideration of a particular product is a consideration of whether or not it should be subject to regulation as a therapeutic good under the provisions of the *Therapeutic Goods Act 1989* (the Act). The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia. The definitions provided in section 3 of the Act are used to determine whether or not a particular product is a therapeutic good for the purposes of regulation under the Act.

TGA's regulatory status for fluoride in water

The Secretary of the Department of Health and Ageing may (under section 7 of the Act), by order published in the *Gazette*, declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of the Act, therapeutic goods. In accordance with this provision of the Act, the Secretary has declared that certain products are not therapeutic goods for the purposes of the Act (Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, available at www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm). This declaration relevantly declares that oral hygiene products for care of the teeth are not therapeutic goods if:

- any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and
- other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal conditions are not claimed to result from use.

Fluoridated water satisfies this requirement and is therefore not a therapeutic good for the purposes of the therapeutic goods regulatory scheme.

We are sorry that we are not able to assist you further.

Kind regards

Debbie
Public Contact Team
Therapeutic Goods Administration

Phone: 1800 020 653
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

----- Forwarded by Debbie Rayment/TGA/Health on 14/12/2012 08:45 AM -----

From: John Teagle
To: <info@tga.gov.au>

Date: 12/12/2012 12:26 PM
Subject: Sodium Fluoride (S7 poison)

Dear Sir/Madam

At their request, I recently conducted an on-line survey about the quality of my Council's water supply.

Before responding to the survey, I did some research on Fluoridation and on the basis on this research, I raised concerns about Sodium Fluoride (S7 poison) being added to the water.

From the reply I received from the Council, my understanding is Councils are required by law to add this poison to our water. As this is a requirement of the NSW Health Department, please advise:

Whether the Sodium Fluoride add to the water supply is of food grade or industrial grade quality?

Whether your Department has ever been required to test the claim that Sodium Fluoride prevents cavities?

Whether your Department has ever considered the concerns raised by the EPA in their Facts Sheets about severe dental Fluorosis, severe Skeletal Fluorosis and Skeletal fractures? See attached.

Whether your Department has collected any information concerning Sodium Fluoride poisoning (an accumulative poison) in Fluoridated communities?

Whether your Department has ever provided the NSW Health Department with any guidelines as to what constitutes a safe dosage of Sodium Fluoride and how to ensure that this dosage is not exceeded? If so, what measures were taken to enforce these recommendations?

As Sodium Fluoride is not only in the drinking water, but also in the food chain (processed foods and drinks are manufactured using tap water) and there is exposure when washing, how has it been possible to safeguard Australians from overdosing on this drug?

I would be grateful if you take these questions seriously as I do have a number of concerns about the way this poison may have affected my health over the years. I have been drinking tap water since the time it was introduced into the NSW water supply more than 50 years ago. During that time, I have had a large number of teeth cavities, requiring fillings and extractions. I was recently informed by my dentist that I have gum disease (receding gums due to calcium deficiency). As Sodium Fluoride depletes the body of calcium I am concerned this may have a lot to do with my dental health issues. Furthermore, I was diagnosed with cancer at the age of thirty (1976) and suffered a heart attack in 2010. As Sodium Fluoride has been linked to cancers and hardening of the arteries, I am also concerned this poison may have impacted adversely on my health.

Best wishes

John